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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/692,559  | 10/24/2003  | Andrew W. Stamford   | CN01472KB           | 9131             |
| 24265   | 7590        | 11/07/2006           | EXAMINER            |                  |
| SCHERING-PLOUGH CORPORATION<br>PATENT DEPARTMENT (K-6-1, 1990)<br>2000 GALLOPING HILL ROAD<br>KENILWORTH, NJ 07033-0530 |             |                      | CHANG, CELIA C      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1625                |                  |

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/692,559

**Applicant(s)**

STAMFORD ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 9-13, 15, 16, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5, 10-13, 15, 16, 21 is/are rejected.
- 7) ☒ Claim(s) 9, 11 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 16, 2006 have been entered and considered carefully.

Claims 4, 6-8, 14, 17-19 have been canceled. Claims 1-3, 5, 9-13, 15-16, 20-21 are pending. Prosecution continuous for the elected invention of bipiperidinyl compounds i.e. the g, j, k, m and n of claim 2. The non-elected compounds stayed withdrawn from consideration and cancellation is recommended.

2. Claims 1-3, 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 13 of the specification it was described that "Solvates" means a physical association of a compound.....". A survey of the specification revealed that none of such solvates or hydrates were found.

Such disclosure provides insufficient enablement for the claimed scope of "all solvates". The specification contains none of the compound, which is a solvate. While a pharmaceutical addition salt can be prepared routinely upon in possession of the claimed compound, the solvate formation is the innate nature of a compound upon contacting certain solvent. Without any description of under what conditions the compounds will form solvate with which compound and completely silent of the existence of any solvate or hydrate, the specification offered mere language rather than possession or enablement of the solvates and the process of claim 21 failed to provided any enablement for a solvate or hydrate.

3. The rejection of claims 10, 12-13, 15-16 under 35 USC 112 first paragraph for treating conditions other than diabetes or obesity is maintained for reason of record.

Applicants attempted to obviate the rejection by changing the term associated with "caused by". Such change not only did not obviate the rejection but created new matter which will be rejected following this rejection.

Art Unit: 1625

NPY Y5 receptor antagonists although found nexus to treating obesity and lowering plasma glucose (see Mashiko p.1796-1797) i.e. treating diabetes, does not provide any cause/etiology relationship between obesity/diabetes and any other disorder of the claims. There is no antecedent basis that obesity caused diabetes or insulin resistance or hyperlipidemia etc. There is no description in the specification that obesity causes lipid mobilization or lipid mobilization causes obesity.

In addition, no definition was found in the specification for the term metabolic disorder. A survey of the literature indicated that there is no definitive meets and bounds of the term (see Merck manual on internet) and in so far as carbohydrate metabolism is concerned, it is referring to glycogen storage diseases, galactosemia etc for which no description or antecedent basis can be found.

4. Claims 10-12,14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As it was delineated supra that the specification disclosed that metabolic disorder such as obesity (p.4), therefore, lacks any antecedent basis for the instant amended scope that metabolic disorder is cause by obesity. Such amended scope is new matter.

Further to the extend that metabolic disorder read on glycogen storage diseases, galactosemia etc. (see Merck manual) no description or antecedent basis can be found in the specification.

Removal of new matter is required. In re Russmussen 210 USPQ 325.

5. Claims 9, 11, 20 are objected to as being dependent upon a rejected base claim, but would be allowable when the base claims are limited to the elected compounds, i.e. non-solvated compounds of claim 2.


Art Unit: 1625

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Oct. 23, 2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625